PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
E SD/RS/2cvc		
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)
PCT/NL95/00336	04/10/95	04/10/94

Applicant

CARDIOVASCULAR CONCEPTS, INC. et al.

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of _____ sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. [X] **Certain claims were found unsearchable** (see Box I).

2. [ ] **Unity of invention is lacking** (see Box II).

3. [ ] The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing

   [ ] filed with the international application.

   [ ] furnished by the applicant separately from the international application,

      [ ] but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.

   [ ] Transcribed by this Authority

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is:

   Figure No. 5

   [ ] as suggested by the applicant.

   [X] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NL95/00336

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 12
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39.1 (iv)

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/NL 95/00336

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO,A,94 04096 (NOVADIS) 3 March 1994	1-6,9, 11,13,14
Y	see abstract; figures see page 5, line 15-20	7,8,10
X	EP,A,0 119 688 (BALKO) 26 September 1984	1-6,9, 11,13,14
	see the whole document	
Y	US,A,4 665 918 (BOSTON SCIENTIFIC CORP.) 19 May 1987 see abstract; figures 9-13	7,10
Y	WO,A,90 01969 (SLEPIAN) 8 March 1990 see figures 13A-D	8
A	EP,A,0 274 846 (ADVANGED SURGICAL INTERVENTION INC.) 20 July 1988	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

Date of the actual completion of the international search
9 January 1996

Date of mailing of the international search report
18. 01. 96

Name and mailing address of the ISA
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Authorized officer
Steenbakker, J

Form PCT/ISA/210 (second sheet) (July 1992)

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-9404096	03-03-94	FR-A-	2694688	18-02-94
EP-A-0119688	26-09-84	US-A-	4512338	23-04-85
US-A-4665918	19-05-87	NONE		
WO-A-9001969	08-03-90	AT-T-	121954	15-05-95
		AU-B-	4191989	23-03-90
		CA-A-	1336755	22-08-95
		DE-D-	68922497	08-06-95
		DE-T-	68922497	14-09-95
		EP-A-	0431046	12-06-91
		EP-A-	0649637	26-04-95
		JP-T-	4501670	26-03-92
		US-A-	5213580	25-05-93
EP-A-0274846	20-07-88	US-A-	4893623	16-01-90
		US-A-	4762128	09-08-88
		AU-B-	649650	02-06-94
		AU-B-	7120091	02-05-91
		AU-B-	7120191	02-05-91
		AU-B-	609431	02-05-91
		AU-B-	8210087	09-06-88
		DE-D-	3789053	24-03-94
		DE-T-	3789053	11-08-94
		ES-T-	2049219	16-04-94
		JP-A-	63214264	06-09-88
		US-A-	5312430	17-05-94
		ZA-A-	8709207	06-06-88

PATENT COOPERATION TRI

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
E SD/RS/2cvc		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/NL 95/ 00336	04/10/1995	04/10/1994
International Patent Classification (IPC) or national classification and IPC		
A61F2/06		
Applicant		
CARDIOVASCULAR CONCEPTS, INC. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consists of a total of 3 sheets.

3. This report contains indications and corresponding pages relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
22/04/1996	23.01.97

Name and mailing address of the IPEA

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/NL95/00336

I. Basis of the report

1. This report has been drawn up on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*

☐ the international application as originally filed

☒ the description, pages 1-9 , as originally filed
pages , filed with the demand
pages , filed with the letter of

☒ the claims, Nos. , as originally filed
Nos. , as amended under Article 19
Nos. , filed with the demand
Nos. 1-13 , filed with the letter of 06/11/96

☒ the drawings, sheets / fig. 1/5-5/5 , as originally filed
sheets / fig. , filed with the demand
sheets / fig. , filed with the letter of

2. The amendments have resulted in the cancellation of:

☐ the description, pages:

☐ the claims, Nos.

☐ the drawings, sheets / fig.

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2 (c)).

4. Additional observations, if necessary:

III. **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-10, 13

because:

☒ the said international application, or the said claims relate to the following subject matter which does not require an international preliminary examination *(specify)*: Nos. 13

☐ the description, claims or drawings *(indicate particular elements below)* or said claims are so unclear that no meaningful opinion could be formed *(specify)*: Nos.

☐ the claims, or said claims are so inadequately supported by the description no meaningful opinion could be formed. Nos.

☒ no international search report has been established for said claims Nos. 1-10, 13 (=original claim 12)

The method set out in claim 13 is regarded as a method of treating the human body by surgery, see Rule 67.1 (iv) PCT.

The subject-matter of the claims 1-10 have been amended with features from the description for which however no international search has been established.

IV. Lack of unity of invention

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

The application lacks unity within the meaning of Article 34(4), Rule 68(1) PCT for the following reasons:

-The subject-matter of independent claim 1 defines an artificial blood vessel inner layer.
- The subject-matter of independent claim 11 defines a surgical introducing means for introducing an artificial blood vessel inner layer ..... into a blood vessel (see also Box V).

Since all the features of claim 11 are already known from US-A-4665918 (=D2, see also Box V) no same or corresponding feature can be found in the subject-matter of respectively independent claims 1 and 11 apart from the features already known from D2.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☒ all parts.

   ☐ the parts relating to claims Nos.

See also Box III.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty	Claims		YES
	Claims	11, 12	NO
Inventive Step	Claims		YES
	Claims	11, 12	NO
Industrial Applicability	Claims	11, 12	YES
	Claims		NO

2. Citations and Explanations

1. US-A-4665918 (=D2) which is considered to represent the most relevant state of the art, for the subject-matter of claim 11 discloses (cf. abstract and figures) an introducing means (suitable) for introducing an artificial blood vessel inner layer into a blood vessel comprising:
-a catheter like element (78);
-widening means (20)..... therein;
-bunging means (20) for blocking off blood .... inner layer; and
-pressure exerting means (see figures 9a-13a) ...blood vessel, the widening, bunging and pressure exerting means have substantially the same diameter as the internal diameter of the bloodvessel into which the artificial blood vessel is introduceable (see figures 9a-13a).
Furthermore D2 discloses that the blood vessel widening means , the bunging means and the pressure exerting means comprise a cone-shaped element (20) associated with a distal end thereof as defined in claim 12.

Hence the present application does not satisfy the criterion set forth in Article 33(2) PCT because the subject-matter of claim 11 and 12 is not new in respect of prior art as defined in the regulations (Rule 64(1)-(3) PCT).

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

Application no. Patent No.	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date (valid claim) *(day/month/year)*
US-A-5522881	04/06/96	28/06/94	

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure *(day/month/year)*	Date of written disclosure referring to non-written disclosure *(day/month/year)*

US-A-5522881 has been introduced by the applicant with the letter of reply dated 31/10/96.

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Reference signs in parentheses should have been inserted in the claims to increase their intelligibility, Rule 6.2(b) PCT. This applies to both the preamble and characterising portion.

The documents D1 and D2 have not been identified in the description nor has the relevant background art disclosed therein been discussed. The requirements of Rule 5.1(a)(ii) PCT are, thus, not fulfilled.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. The various definitions of the invention given in independent claims 1 and 11 are such that the claims as a whole are not clear and concise, contrary to Article 6 PCT. The claims should be recast to include only the minimum necessary number of independent claims in any one category, with dependent claims as appropriate (Rule 6.4(a)-(c) PCT).

   In the present case it is considered appropriate to use only a single independent claim.

NEW CLAIMS

1. An artificial blood vessel inner layer, made from synthetic material, such as an artificial tunica intima or the like for replacing a section of blood vessel inner layer previously removed from a blood vessel and/or for covering a predetermined length of damaged blood vessel inner layer,
comprising diameter arranging means for increasing and/or decreasing the diameter of the artificial blood vessel inner layer,
characterized in that said artificial blood vessel layer in turn comprises one or more end sections folded back over the outer surface thereof to lie unjoined therealong, in which fold(s) the diameter arranging means are disposed.

2. An artificial blood vessel inner layer according to claim 1 wherein the diameter arranging means comprise a length of memory metal preprogrammed to expand and/or contract at a determined temperature.

3. An artificial blood vessel inner layer according to claim 1 wherein the diameter arranging means comprise an expandable gauze.

4. A blood vessel treating assembly, comprising:

- an artificial blood vessel inner layer according to any of the claims 1-3 and,
- introducing means for introducing the artificial blood vessel inner layer into a blood vessel.

5. An assembly according to claim 6, further comprising at least one sheath-like protective cover.

6. An assembly according to claims 4 or 5 wherein the introducing means comprise at least one

catheter-like element associated with the artificial blood vessel inner layer.

7. An assembly according to any of the claims 4-6 further comprising widening means for widening out of the blood vessel in order to facilitate introduction of the blood vessel treating assembly therein.

8. An assembly according to any of the claims 4-7 further comprising bunging means for substantially blocking off the passage of blood into the assembly during introduction of the assembly into the blood vessel.

9. A blood vessel treating assembly according to any of the claims 4-8 further comprising pressure exerting means for exerting pressure onto the artificial blood vessel inner layer, when the latter is in position within the blood vessel.

10. A blood vessel treating assembly according to claim 9 wherein the blood vessel widening means, the bunging means and the pressure exerting means comprise a cone-shaped element associated with the front of the introducing means.

11. Introducing means for introducing an artificial blood vessel inner layer according to any of the claims 1-10 into a blood vessel, comprising:

- a catheter-like element,
- widening means for widening out of the blood vessel in order to facilitate introduction of the artificial blood vessel inner layer therein,
- bunging means for substantially blocking off the passage of blood during introduction of the artificial blood vessel inner layer,
- pressure exerting means for exerting pressure onto the artificial blood vessel inner layer, when the latter is in position within the blood vessel,

characterized in that the widening, bunging and pressure exerting means have substantially the same diameter as the internal diameter of the blood vessel into which the artificial blood vessel is introduceable.

12. Introducing means according to claim 11 wherein the blood vessel widening means, the bunging means and the pressure exerting means comprise a cone-shaped element associated with a distal end of thereof.

13. A method of replacing a previously removed inner layer of a blood vessel and/or for covering a predetermined length of damaged blood vessel inner layer comprising the steps of inserting a blood vessel treating assembly according to claims 4-11, via an incision, upto a predetermined distance into a blood vessel, removing the protective sheath from around the assembly whereafter the artificial blood vessel inner layer is expanded against the blood vessel walls, the catheter-like element then being removed from the blood vessel, the cone-like element further forcing the artificial blood vessel inner layer into position as it does so, and joining the end of the artificial blood vessel inner layer to the existing blood vessel near the incision.

catheter-like element associated with the artificial blood vessel inner layer.

7. An assembly according to any of the claims 4-6 further comprising widening means for widening out of the blood vessel in order to facilitate introduction of the blood vessel treating assembly therein.

8. An assembly according to any of the claims 4-7 further comprising bunging means for substantially blocking off the passage of blood into the assembly during introduction of the assembly into the blood vessel.

9. A blood vessel treating assembly according to any of the claims 4-8 further comprising pressure exerting means for exerting pressure onto the artificial blood vessel inner layer, when the latter is in position within the blood vessel.

10. A blood vessel treating assembly according to claim 9 wherein the blood vessel widening means, the bunging means and the pressure exerting means comprise a cone-shaped element associated with the front of the introducing means.

11. Introducing means for introducing an artificial blood vessel inner layer according to any of the claims 1-10 into a blood vessel, comprising:

- a catheter-like element,
- widening means for widening out of the blood vessel in order to facilitate introduction of the artificial blood vessel inner layer therein,
- bunging means for substantially blocking off the passage of blood during introduction of the artificial blood vessel inner layer,
- pressure exerting means for exerting pressure onto the artificial blood vessel inner layer, when the latter is in position within the blood vessel,

characterized in that the widening, bunging and pressure exerting means have substantially the same diameter as the internal diameter of the blood vessel into which the artificial blood vessel is introduceable.

AMENDED SHEET
IPEA/EP

12. Introducing means according to claim 11 wherein the blood vessel widening means, the bunging means and the pressure exerting means comprise a cone-shaped element associated with a distal end of thereof.

13. A method of replacing a previously removed inner layer of a blood vessel and/or for covering a predetermined length of damaged blood vessel inner layer comprising the steps of inserting a blood vessel treating assembly according to claims 4-11, via an incision, upto a predetermined distance into a blood vessel, removing the protective sheath from around the assembly whereafter the artificial blood vessel inner layer is expanded against the blood vessel walls, the catheter-like element then being removed from the blood vessel, the cone-like element further forcing the artificial blood vessel inner layer into position as it does so, and joining the end of the artificial blood vessel inner layer to the existing blood vessel near the incision.